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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,276	12/09/2003	Alain Tornier	14542	2602

293 7590 04/25/2006

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT PAPER NUMBER

1744

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,276

Applicant(s)

TORNIER, ALAIN

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolais (EP 982236) in view of Hamilton et al (EP 737481) in view of Ahlqvist et al (US 5881534).

With respect to claims 1-3 and 8-10, Nicolais teaches a process for the sterile packaging of a prosthetic implant **10** wherein the implant is placed in a flexible, gas-impermeable sachet **18** under vacuum and the sachet **18** is heat sealed. The sachet containing the implant is then placed within a flexible gas-impermeable envelope **20** which is also heat sealed. This sealed envelope **20** containing the sachet and implant is folded upon itself and placed within a rigid outer container **28** to protect the implant. See Figure 2; paragraphs [0012]-[0027]. Nicolais is silent with respect to the implant (hip joint prosthesis) being made of polyethylene or to forming an inert gaseous atmosphere within the envelope before sealing.

Hamilton et al discloses that it was known in the art at the time of the invention to fabricate artificial joints from polymeric materials, such as ultrahigh molecular weight polyethylene and to sterilize these joints using radiation. See Abstract; page 1, lines 7-10. It would have been obvious to one of ordinary skill in the art to employ the sterile packaging method of Nicolais to package and sterilize implants fabricated from polyethylene since they are

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safely sterilized by radiation and since polyethylene is a common material from which artificial joints are fabricated.

Ahlqvist et al teaches that when either an article or the packaging in which the article is enclosed is fabricated from a polymer, such as polyethylene, it is necessary to remove oxygen from the atmosphere surrounding the polyethylene so that during radiation the formation of free radicals is minimized. To remove the oxygen, Ahlqvist et al discloses that the article or container be surrounded by an inert gas (nitrogen). See col.5, line 60 to col.6, line 52.

Since Nicolais alone teaches forming the envelope **20** of a polymeric material, such as polyethylene, it would have been obvious to form an inert gas atmosphere within the envelope **20** of Nicolais before sealing, thus minimizing free radical damage to the envelope.

As to claim 4, Nicolais teaches that the sachet **18** may be formed of laminates of different materials (paragraphs [0020]-[0021]) but does not teach a laminate containing aluminum for the sachet **18**. Ahlqvist et al discloses a gas-impermeable container suitable for radiation sterilization that preferably contains an aluminum layer. See col.6, lines 41-47. It would have been obvious to one of ordinary skill in the art to choose a gas-impermeable packaging material known in the art to be sealable, stable over long periods of storage, and capable of withstanding irradiation. As the packaging material of Ahlqvist et al meets these requirements and as Nicolais is not limited to a particular packaging material, it would have been obvious to one of ordinary skill in the art to choose the aluminum laminate packaging material of Ahlqvist et al for the sachet **18** of Nicolais.

With respect to claim 5, Nicolais teaches that the envelope **20** can be fabricated from “flexible polymeric films” that are gas impermeable. Suggested materials include polyethylene

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and nylon (polyamide). See paragraph [0023]. However, Nicolais does not disclose a film containing both nylon and polyethylene. Hamilton et al teaches sealed, gas-impermeable packaging material that is irradiated for sterilization of the articles within. Suggested materials includes a multilayered film containing both nylon and polyethylene. See page 3, lines 6-14. As this packaging material fulfills the requirements of Nicolais (gas-impermeable, sealable, and radiation sterilizable), one would have found it obvious to use the packaging material of Hamilton et al. for the envelope **20** of Nicolais.

As to claims 6 and 7, the combination of Nicolais with Ahlqvist et al teaches removing oxygen from the envelope **20** (presumably by vacuum) and filling the envelope with an inert gas. Ahlqvist et al does not disclose a pressure to which one should fill the inert gas. However, as Nicolais teaches keeping the sachet **18** under a vacuum, it would have been obvious to also maintain the inert gas-filled envelope **20** below atmospheric. Moreover, in order to control the introduction of inert gas into the envelope it is deemed obvious to employ suitable control means, such as calibration, for accuracy.

Response to Arguments

3. Applicant's arguments filed 13 February 2006 have been fully considered but they are not persuasive.

4. With respect to the Ahlqvist et al. reference, Applicant argues that "the reference does not contemplate filling an outer envelope with an inert gas, as it states "An important advantage of the invention is the possibility of sealing the gas impermeable package in air, without the use of inert gases, and still be able to obtain an advantageous γ -radiation sterilization without side

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reactions.”” While the Examiner agrees that Ahlqvist et al. does indeed teach that packaging the article using an oxygen absorber is preferable to use of an inert gas, one cannot simply ignore the clear teachings of Ahlqvist et al. that the use of an inert gas in the packaging process is also an option. As set forth in the rejection *supra*, Ahlqvist et al. states that the “package containing the polymeric medical article or the polymeric container filled with a product...can optionally be sealed in an oxygen depleted atmosphere in the presence of nitrogen or another suitable inert gas.” See col.6, lines 48-52. This method may be a non-preferred embodiment, but it is a disclosed embodiment nonetheless and more importantly, is a disclosed solution to the problem of oxidation of the polymeric packaging material. Moreover, it has been held that references are not limited to their preferred embodiments. In re Boe, 148 USPQ 507 (CCPA 1966). All of the disclosure in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. Thus, in In re Smith, 32 CCCPA 959, 148 F.2d 351, 65 USPQ 167; in In re Nehrenberg, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; and in In re Watanabe, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350, the court affirmed rejections based on art which the court concluded rendered the claimed invention obvious to those of ordinary skill in the art despite the fact that the art teachings relied upon in all three cases were phrased in terms of a non-preferred embodiment or as being unsatisfactory for the intended purpose.

5. Furthermore, Applicant submits that neither the primary nor the secondary references recognize the “desire to provide an outer envelop filled with an inert gas to provide a safety barrier to protect an implant should the inner sachet be compromised” and thus cannot be “modified to teach the characterizing elements of the present invention” (see page 12, lines 12-18 of the Response). In response, the Examiner notes that the fact that Applicant has recognized

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another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In fact, where the invention is unpatentable under 35 U.S.C. 103, it is immaterial that Applicant may have disclosed an obvious or unobvious further purpose or advantage in the invention. See *In re Graf*, 145 USPQ 197 (CCPA 1965); *In re Finsterwalder*, 168 USPQ 530 (CCPA 1971).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

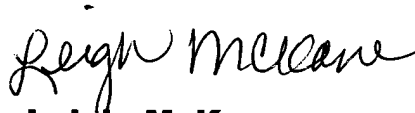
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leigh McKane
Primary Examiner
Art Unit 1744

elm
19 April 2006